11-0900-17586-1

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS
FOR THE DEPARTMENT OF HEALTH

In the Matter of the Proposed Amendments to Rules Governing Newborn Screening, Minnesota Rules, Chapter 4615

REPORT OF THE ADMINISTRATIVE LAW JUDGE

A hearing concerning the above rules was held by Administrative Law Judge Barbara L. Neilson at 9:00 a.m. on January 23, 2007, at the Minnesota Department of Health, Freeman Building, Room B145, 625 Robert Street North, St. Paul, Minnesota.

That hearing and this Report are part of a rulemaking process that must occur under the Minnesota Administrative Procedure Act[1] before an agency can adopt rules. The Legislature has designed that process to ensure that state agencies here, the Minnesota Department of Health (Department or Agency) have met all the requirements that Minnesota law specifies for adopting rules. Those requirements include assurances that the proposed rules are necessary and reasonable and that any modifications that the Agency may have made after the proposed rules were initially published do not result in them being substantially different from what the Agency originally proposed. The rulemaking process also includes a hearing to allow the Agency and the Administrative Law Judge reviewing the proposed rules to hear public comment about them.

Patricia Segal Freeman, Policy Analyst/Rule Writer, Department of Health, Immunization, Tuberculosis and International Health Section, P.O. Box 9441, St. Paul, MN 55440-9441, appeared at the rule hearing on behalf of the Department of Health. Mark McCann, Supervisor of the Department's Newborn Screening Program, Steven Johnson, J.D., Chair of the Minnesota's Newborn Screening Advisory Committee, and Susan Berry, M.D., Professor and Director of the Division of Genetics and Metabolism of the University of Minnesota's Department of Pediatrics, testified on behalf of the Department in support of the proposed rules. Approximately 35 persons attended the hearing; seven signed the hearing register. The hearing continued until all interested persons, groups or associations had an opportunity to be heard concerning the proposed amendments to these rules.

After the hearing ended, the Administrative Law Judge kept the administrative record open for another twenty calendar days – that is, until February 12, 2007 – to allow interested persons and the Department to submit written comments. Following the initial comment period, Minnesota law[2] required that the hearing record remain open for another five business days to allow

[1] Minn. Stat. §§ 14.131 through 14.20.
[2] Minn. Stat. § 14.15, subd. 1.

interested parties and the Department to respond to any written comments. Numerous members of the public submitted comments before, during, and after the rulemaking hearing. The Department submitted post-hearing comments. The rulemaking record closed for all purposes on February 20, 2007.

NOTICE

The Department must make this Report available for review by anyone who wishes to review it for at least five working days before the Department takes any further action to adopt final rules or to modify or withdraw the proposed rules. If the Department makes changes in the rules other than those recommended in this report, it must submit the rules, along with the complete hearing record, to the Chief Administrative Law Judge for a review of those changes before it may adopt the rules in final form.

Because the Administrative Law Judge has determined that the proposed rules are defective in certain respects, state law requires that this Report be submitted to the Chief Administrative Law Judge for his approval.[3] If the Chief Administrative Law Judge approves the adverse findings contained in this Report, he will advise the Department of actions that will correct the defects, and the Department may not adopt the rules until the Chief Administrative Law Judge determines that the defects have been corrected. However, if the Chief Administrative Law Judge identifies defects that relate to the issues of need or reasonableness, the Department may either adopt the actions suggested by the Chief Administrative Law Judge to cure the defects or, in the alternative, submit the proposed rules to the Legislative Coordinating Commission for the Commission's advice and comment. The Department may not adopt the rules until it has received and considered the advice of the Commission. However, the Department is not required to wait for the Commission's advice for more than 60 days after the Commission has received the Department's submission.

If the Department elects to adopt the actions suggested by the Chief Administrative Law Judge and make no other changes and the Chief Administrative Law Judge determines that the defects have been corrected, it may proceed to adopt the rules. If the Department makes changes in the rules other than those suggested by the Administrative Law Judge and the Chief Administrative Law Judge, it must submit copies of the rules showing its changes, the rules as initially proposed, and the proposed order adopting the rules to the Chief Administrative Law Judge for a review of those changes before it may adopt the rules in final form.

After adopting the final version of the rules, the Department of Health must submit them to the Revisor of Statutes for a review of their form. If the Revisor of Statutes approves the form of the rules, the Revisor will submit certified copies to the Administrative Law Judge, who will then review them and file them with the Secretary of State. When they are filed with the Secretary of State, the

[3] Minn. Stat. § 14.15, subds. 3-4.

Administrative Law Judge will notify the Department, and the Department will notify those persons who requested to be informed of their filing.

Based upon all the testimony, exhibits, and written comments, the Administrative Law Judge makes the following:

FINDINGS OF FACT

I. Nature of the Proposed Rules

1. The Minnesota Department of Health's newborn screening program has been in operation in Minnesota since 1965. For many years, the program screened only for phenylketonuria (PKU). Currently, the program screens for more than fifty disorders. Hospitals collect blood from newborns and submit the dried blood spot specimens to the Department's Public Health Laboratory. Each year, more than 73,000 newborns are screened in Minnesota and approximately 100 infants are found to have a confirmed disorder. The opportunity for early medical interventions may prevent severe disabilities or death.[4] This rulemaking proceeding involves a proposal by the Minnesota Department of Health to amend and add additional language to rule provisions relating to the newborn screening program currently set forth in Minnesota Rules Chapter 4615. The newborn screening rules were last amended in 2000. In the current set of proposed rules, the Department seeks to update the existing rules to reflect statutory changes made to the program in 2003.[5] The proposed rules also are intended to reflect new technological advances and clarify the roles of the Department, hospitals, and health care providers.[6]

2. The 2003 statutory changes deleted references to hemoglobinopathy, phenylketonuria, and "inborn errors of metabolism" throughout the newborn screening statutes and substituted the phrase "heritable and congenital disorders." Section 144.125, subd. 2, was amended to authorize the Commissioner of Health to periodically revise the list of tests to be administered for determining the presence of a heritable or congenital disorder, without the need to engage in rulemaking, in order to "reflect advances in medical science, new and improved testing methods, or other facts that will improve public health." A requirement was added to Minn. Stat. § 144.125, subd. 3, that persons performing testing advise parents that the blood or tissue samples used to perform testing as well as the results of the testing may be retained by the Department, tell them of the benefit of retaining the blood or tissue sample, and inform them that they could decline to have the tests or elect to have the tests but require that all blood samples and records of test results be destroyed within 24 months of the testing. The amendments specified that any such objection or election to have results destroyed be recorded on a form. The 2003 statutory changes also added a new section 144.1255 that directed the Commissioner to create an advisory committee to provide advice and

[4] Statement of Need and Reasonableness ("SONAR") at 1.
[5] Minn. Stat. § 144.125 – 144.128.
[6] SONAR at 2; Ex. M (Testimony of M. McCann and S. Berry).

recommendations concerning tests and treatments for heritable and congenital disorders and prescribed certain functions and objectives to be carried out by the advisory committee, including "discussion and assessment of ethical considerations surrounding the testing, treatment, and handling of data and specimens" generated by the newborn testing requirements and "providing advice and recommendations to the commissioner concerning tests and treatments for heritable and congenital disorders." Finally, the amendments enacted in 2003 revised section 144.128 to require the Commissioner to notify newborns' physicians of the test results.[7]

3. The Legislature also amended the newborn screening statute in 2006. These amendments added language to Minn. Stat. § 144.128 that required the Commissioner of Health to "prepare a separate form for use by parents or by adults who were tested as minors to direct that blood samples and test results be destroyed," "comply with a destruction request within 45 days after receiving it," and "notify individuals who request destruction of samples and test results that the samples and test results have been destroyed."[8]

4. Among other things, the current set of proposed rules define "newborn screening panel" to mean the list of genetic and/or congenital diseases that will be the subject of newborn screening, as determined by the Commissioner of Health. The proposed rules also expand the definition of "responsible party" and assign duties to a newly-defined "primary medical care provider" rather than an "attending physician." The rules clarify and expand the duties of the responsible party, the primary medical care provider and the Department to establish practices ensuring that all newborns have newborn screening specimens collected and submitted to the Department prior to discharge or before 48 hours of life, unless a parent opts out of the screening; establish mechanisms for prompt follow-up to testing as necessary and appropriate by the responsible party, the Department and the primary medical care provider; and establish procedures for parents to opt out of the screening or to request that a child's blood sample and test results be destroyed.

5. The Department formed a Newborn Screening Rule Advisory Committee to represent the various parties affected by the proposed rule amendments. The Advisory Committee included a parent as well as representatives from hospitals and clinics, medical associations, health plans, the Center for Bioethics, and the Minnesota Civil Liberties Union. The Advisory Committee convened on November 16, 2005 and March 1, 2006, and participants were given an opportunity to share their views and ask questions about the proposed amendments to the rules. After each meeting, MDH modified the proposed amendments in response to Advisory Committee comments. MDH maintained contact with advisory committee members through e-mail and also asked Advisory Committee members to distribute a draft of the proposed amendments to their organizational lists during the Request for Comment period. As a result of this process, the MDH received comments on

[7] 2003 Minn. Laws, 1 Special Session, Chapter 14, Article 7, Sections 26-28.
[8] 2006 Minn. Laws, Chapter 253, Section 9.

the proposed amendments to the rules through the Request for Comments, the Advisory Committee, and the distribution of the proposed rules by MDH and Advisory Committee members.[9]

II. Rulemaking Legal Standards

6. Under Minn. Stat. § 14.14, subd, 2, and Minn. Rule 1400.2100, one of the determinations which must be made in a rulemaking proceeding is whether the agency has established the need for and reasonableness of the proposed rule by an affirmative presentation of facts. In support of a rule, the agency may rely on legislative facts, namely general facts concerning questions of law, policy and discretion, or the agency may simply rely on interpretation of a statute, or stated policy preferences.[10] The Department prepared a Statement of Need and Reasonableness ("SONAR") in support of the proposed rules. At the hearing, the Department primarily relied upon the SONAR as its affirmative presentation of need and reasonableness for the proposed amendments. The SONAR was supplemented by comments made by the Agency Panel at the public hearing.

7. The question of whether a rule has been shown to be reasonable focuses on whether it has been shown to have a rational basis, or whether it is arbitrary, based upon the rulemaking record. Minnesota case law has equated an unreasonable rule with an arbitrary rule.[11] Arbitrary or unreasonable agency action is action without consideration and in disregard of the facts and circumstances of the case.[12] A rule is generally found to be reasonable if it is rationally related to the end sought to be achieved by the governing statute.[13] The Minnesota Supreme Court has further defined an agency's burden in adopting rules by requiring it to "explain on what evidence it is relying and how the evidence connects rationally with the agency's choice of action to be taken."[14] An agency is entitled to make choices between possible approaches as long as the choice made is rational. Generally, it is not the proper role of the Administrative Law Judge to determine which policy alternative presents the "best" approach since this would invade the policy-making discretion of the agency. The question is rather whether the choice made by the agency is one a rational person could have made.[15]

8. In addition to need and reasonableness, the Administrative Law Judge must also assess whether the Department complied with the rule adoption procedure, whether the rule grants undue discretion, whether the Department has statutory authority to adopt the rule, whether the rule is unconstitutional or

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[9] *See* SONAR at 2 and Attachment D.
[10] *Mammenga v. Department of Human Services*, 442 N.W.2d 786 (Minn. 1989); *Manufactured Housing Institute v. Pettersen*, 347 N.W. 2d 238, 244 (Minn. 1984).
[11] *In re Hanson*, 275 N.W. 2d 790 (Minn. 1978); *Hurley v. Chaffee*, 231 Minn. 362. 367, 43 N.W. 2d 281, 284 (1950).
[12] *Greenhill v. Bailey*, 519 F.2d 5, 19 (8th Cir. 1975).
[13] *Mammenga*, 442 N.W.2d at 789-90; *Broen Memorial Home v. Minnesota Department of Human Services*, 364 N.W.2d 436, 44 (Minn. Ct. App. 1985).
[14] *Manufactured Housing Institute*, 347 N.W.2d at 244.
[15] *Federal Security Administrator v. Quaker Oats Co.*, 318 U.S. 218, 233 (1943).

illegal, whether the rule constitutes an undue delegation of authority to another entity, or whether the proposed language is not a rule.[16]

9. Because the Department suggested changes to part 4615.0400, subparts 3, 4a and 5, and part 4615.0700 of the proposed rules after original publication of the rule language in the State Register, it is also necessary for the Administrative Law Judge to determine if the new language is substantially different from that which was originally proposed.[17] The standards to determine if the new language is substantially different are found in Minn. Stat. § 14.05, subd. 2. The statute specifies that a modification does not make a proposed rule substantially different if "the differences are within the scope of the matter announced . . . in the notice of hearing and are in character with the issues raised in that notice," the differences "are a logical outgrowth of the contents of the . . . notice of hearing and the comments submitted in response to the notice," and the notice of hearing "provided fair warning that the outcome of that rulemaking proceeding could be the rule in question." In reaching a determination regarding whether modifications are substantially different, the Administrative Law Judge is to consider whether "persons who will be affected by the rule should have understood that the rulemaking proceeding . . . could affect their interests," whether "the subject matter of the rule or issues determined by the rule are different from the subject matter or issues contained in the . . . notice of hearing," and whether "the effects of the rule differ from the effects of the proposed rule contained in the . . . notice of hearing."[18]

III. Compliance with Procedural Rulemaking Requirements

10. On December 12, 2005, the Department published a Request for Comments pertaining to the proposed rules in 30 State Register 616.[19]

11. The Department mailed the Request for Comments to all persons who had registered to be on the Department's rulemaking mailing list under Minnesota statutes, section 14.14, subdivision 1a; posted the proposed rules, the dual notice, the SONAR, and a fact sheet containing a summary of the substantive amendments on the Department's Newborn Screening Rulemaking website at www.health.state.mn.us/divs/phl/newborn/rulechange.html; provided a copy of the dual notice, the SONAR, the fact sheet containing a summary of the substantive amendments, and a web link to the proposed rules to members of the Advisory Committee, and also asked them to forward this information to the organizations they represent and their colleagues; provided all of the same information via e-mail, directly or through a listserv, to various individuals, groups and organizations (including the Minnesota Medical Association, the Minnesota Academy of Family Physicians, the Minnesota chapter of the American Academy of Pediatrics, the Minnesota Council of Health Plans, the Minnesota Hospital Association, the Minnesota Nurses Association, and the Department's Minnesota

[16] Minn. R. 1400.2100.
[17] *See* Minn. Stat. §§ 14.15, subd.3, and 14.05, subd. 2.
[18] Minn. Stat. § 14.05, subd. 2.
[19] Ex. A.

laboratory system list, which includes approximately 160 laboratories, including public health and private clinical laboratories which serve Minnesota residents) and requested that, when possible, these organizations post the information on their websites and send it out to their listservs; and published information on the Request for Comments in the Department's weekly briefing.[20]

12. On October 17, 2006, the Department requested the scheduling of a hearing regarding the proposed rules and filed the following documents with the Chief Administrative Law Judge:

a. a copy of the proposed rules certified by the Revisor of Statutes;

b. a copy of the Dual Notice of Hearing proposed to be issued; and

c. a draft of the Statement of Need and Reasonableness ("SONAR").

13. On October 24, 2006, the Department's Dual Notice of Hearing and Additional Notice Plan were approved by the Administrative Law Judge.

14. On November 15, 2006, the Department mailed a copy of the SONAR to the Legislative Reference Library as required by law.[21]

15. On November 16, 2006, the Department mailed the Dual Notice of Hearing and a summary of the proposed rules to all persons and associations on the Department's rulemaking mailing list.[22] On November 17, 2006, the Department also provided a copy of the Dual Notice of Hearing, the SONAR, a summary of the substantive rule changes, and a web link to the proposed rules to members of the Advisory Committee and asked them to forward this information to their colleagues and the organizations they represent. Between November 17, 2006 and November 30, 2006, the Department sent copies of the proposed rules, the Dual Notice of Hearing, the SONAR, and the summary of substantive rule changes through e-mail and listservs to health care providers who provide medical care to infants, the Minnesota Medical Association, the Minnesota Academy of Family Physicians, the Minnesota Chapter of the American Academy of Pediatrics, the Minnesota Council of Health Plans, the Minnesota Hospital Association, the Minnesota Nurses Association, medical laboratories, and the Department's Minnesota Laboratory System list, which includes approximately 160 public health and private clinical laboratories that serve Minnesota residents.[23]

[20] SONAR at 2 and Attachment C.
[21] Ex. E; Minn. Stat. § 14.131 and Minn. R. 1400.2220, subp. 1(E).
[22] Ex. G.
[23] Ex. H.

16. The Notice of Hearing and SONAR were mailed on November 16, 2006, to the chairs and ranking minority members of the legislative policy and budget committees as well as to Representative Mary Liz Holberg.[24]

17. On November 20, 2006, a copy of the proposed rules and the Notice of Hearing were published at 31 State Register 663.[25] Those documents, the SONAR, and a rule summary were also posted on the Department's web site on November 17, 2006. The Department also issued a press release on November 21, 2006, concerning the proposed rules.[26]

18. Approximately sixty-nine persons requested that a hearing be held on the proposed rules.[27]

19. On December 27, 2006, the Department mailed a Notice of Hearing to all persons who requested a hearing and who provided their mailing address, and e-mailed a Notice of Hearing to all persons who requested a hearing through e-mail but did not provide their mailing address.[28]

20. On the day of the hearing, the Department placed the following documents into the record:

a. the Request for Comments as published in the State Register (Exhibit A);

b. copies of the Dual Notice as mailed and published in the State Register, the proposed rules as certified by the Revisor of Statutes, and the SONAR, along with certificates of mailing to the Legislative Reference Library and the Certificates of Mailing the Notice of Hearing and of Accuracy of the Mailing List and the Certificate of Additional Notice (Exhibits C, D, E, F, G and H);

c. copies of the written comments on the proposed rules received by the Agency during the comment period (Exhibit I);

d. the Certificate of Sending the Notice and the Statement of Need and Reasonableness to Legislators (Exhibit K);

e. letters in support of the proposed rules received from the American Academy of Pediatrics, the Minnesota Council of Health Plans, the March of Dimes, the Mayo Clinic, the

[24] Ex. H.
[25] Ex. F.
[26] Ex. H. The certificate states that the date was November 21, 2007, but the Administrative Law Judge assumes that it was intended to read November 21, 2006.
[27] Ex. I.
[28] Ex. K.

CARES Foundation, Hennepin County Medical Center, Christine Doran, and the Missouri Newborn Screening Program (Exhibit L);

f. written versions of the testimony in support of the proposed rules given by members of the Agency panel at the hearing on January 23, 2007 (Exhibit M);

g. proposed rule changes submitted to the Administrative Law Judge at the January 23, 2007 hearing (Exhibit N); and

h. copies of the MDH Newborn Screening Brochure given to new patients at Birthing Centers and a one-page fact sheet intended for use as a prenatal educational tool (Exhibit O).

21. The Administrative Law Judge concludes that the Department met all of the procedural requirements established by statute and rule.

IV. Statutory Authority

22. As statutory authority for the proposed rule changes, the Department cites Minn. Stat. § 144.128. Minn. Stat. § 144.128 states that the Commissioner of Health shall "adopt rules to carry out sections 144.125 to 144.128."[29]

23. The list of the Commissioner's duties set forth in Minn. Stat. §§ 144.125 to 144.128 includes prescribing procedures to be followed by institutions and individuals required by the statute to perform newborn screening, including testing, recording and reporting test results; charging laboratory service fees to cover "the costs of conducting the tests and implementing and maintaining a system to follow-up infants" who have heritable or congenital disorders; periodically revising the list of tests to be administered; and appointing an advisory committee to provide recommendations regarding tests and treatments for heritable and congenital disorders and assess information on tests, treatments, medical conditions caused by heritable and congenital disorders, the benefits versus the costs of testing, and the ethical concerns relating to testing, treatment and the "handling of data and specimens generated by the testing requirements." In addition, Minn. Stat. § 144.128 requires that the Commissioner:

(1) notify the physicians of newborns tested of the results of the tests performed;

[29] The SONAR cites Minn. Stat. § 144.128 (4) as the statutory authority for this rulemaking. Pursuant to changes made during the 2006 legislative session, the rulemaking authority is now at Minn. Stat. § 144.128 (7).

(2) make referrals for the necessary treatment of diagnosed cases of heritable and congenital disorders when treatment is indicated;

(3) maintain a registry of the cases of heritable and congenital disorders detected by the screening program for the purpose of follow-up services;

(4) prepare a separate form for use by parents or by adults who were tested as minors to direct that blood samples and test results be destroyed;

(5) comply with a destruction request within 45 days after receiving it;

(6) notify individuals who request destruction of samples and test results that the samples and test results have been destroyed; and

(7) adopt rules to carry out sections 144.125 to 144.128.

24. The Administrative Law Judge finds that the Department has general statutory authority to adopt the proposed rules. Issues relating to the Department's statutory authority to adopt specific provisions of the proposed rules shall be discussed below.

V. Impact on Farming Operations

25. Minn. Stat. § 14.111 imposes an additional notice requirement when rules are proposed that affect farming operations. In essence, the statute requires that an agency must provide a copy of any such proposed rule change to the Commissioner of Agriculture at least thirty days prior to publishing the proposed rule in the State Register.

26. The proposed rules do not impose restrictions or have a direct impact on fundamental aspects of farming operations. The Administrative Law Judge finds that the proposed rule change will not affect farming operations in Minnesota, and thus finds that no additional notice is required.

VI. Additional Notice Requirements

27. Minn. Stat. § 14.131 requires that an agency include in its SONAR a description of its efforts to provide additional notification to persons or classes of persons who may be affected by the proposed rule or must explain why these efforts were not made. On October 24, 2006, the Office of Administrative Hearings reviewed and approved the Department's additional notice plan.

28. The Department made significant efforts to inform and involve interested and affected parties in this rulemaking. It mailed the Request for Comments to all persons who had registered to be on the Department's rulemaking mailing list under Minnesota statutes, section 14.14, subdivision 1a; posted the proposed rules, the dual notice, the SONAR, and a fact sheet containing a summary of the substantive amendments on the Department's Newborn Screening Rulemaking website; provided a copy of the dual notice, the SONAR, the fact sheet containing a summary of the substantive amendments, and a web link to the proposed rules to members of the Advisory Committee, and also asked them to forward this information to their colleagues and the organizations they represent; provided all of the same information via e-mail, directly or through a listserv, to various individuals, groups and organizations (including the Minnesota Medical Association, the Minnesota Academy of Family Physicians, the Minnesota chapter of the American Academy of Pediatrics, the Minnesota Council of Health Plans, the Minnesota Hospital Association, the Minnesota Nurses Association, and the Department's Minnesota laboratory system list, which includes approximately 160 laboratories, including public health and private clinical laboratories which serve Minnesota residents) and requested that, when possible, these organizations post the information on their websites and send it out to their listservs; and published information on the Request for Comments in the Department's weekly briefing.

29. The Administrative Law Judge finds that the Department fulfilled its additional notice requirement.

VII. Other Statutory Requirements for the SONAR

A. Cost and Alternative Assessments

30. Minn. Stat. § 14.131 requires an agency adopting rules to include in its SONAR:

> a. a description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule;
>
> b. the probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues;
>
> c. a determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule;
>
> d. a description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the

agency and the reasons why they were rejected in favor of the proposed rule;

e. the probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals;

f. the probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals; and

g. an assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference.

31. With respect to the first requirement, the Department indicated in the SONAR that the classes of persons who will be affected by the proposed rule are hospitals and birth attendants responsible for collecting the blood specimens, health care providers responsible for the infant's care after the baby is discharged from the hospital or birthing attendant, the Minnesota Department of Health, parents and guardians of newborns in Minnesota, and the newborns themselves. It stated that the proposed rules do not change who is required to report, but rather the roles and responsibilities of those involved in the process.[30] The Department identified two classes of persons who will bear the costs of the proposed rule. First, the Department states that it will bear the cost of developing forms required by the proposed revisions. Second, the Department identified birthing centers and birthing attendants because they currently purchase specimen cards from the Department at a cost of $61 per specimen card, which was increased from $21 by the Legislature during the 2003 legislative session. The Department asserted that this cost is typically reimbursed by insurance and the increase was not opposed when it was considered and passed by the Legislature. The fee covers testing for all of the disorders listed in the newborn screening panel and the necessary follow-up.[31] Because the increased cost is mandated by the statute and was implemented in 2003, the proposed rule does not create an increase in cost for the birthing centers or the birthing attendants.[32] Finally, the Department identified the following classes of persons as those who will benefit from the proposed rule: Minnesota newborns and children, who will have the opportunity to be screened for disorders that cause serious morbidity and mortality and receive appropriate early diagnosis and treatment; Minnesota parents and guardians, who will receive pertinent information on treatment in the cases where there is a confirmed diagnosis; primary medical care providers and other responsible parties, whose duties are clarified by these rules; Minnesota's medical and health systems, which will experience the cost savings that comes

[30] SONAR at 3.
[31] SONAR at 4.
[32] *See* Minn. Stat. § 144.125.

with early detection and treatment of the disorders for which the newborns are screened; and Minnesota's educational and social service systems, which will save hundreds of thousands of dollars in services which would otherwise have had to be provided to children who would have suffered significant long-term consequences because of failures to detect and treat the disorders as soon as possible.[33]

32. With respect to the second requirement, the Department estimated that the probable costs to the Department for implementing the proposed rule amendments would be minimal because costs for developing forms and educating parties about the changes established by the rule will be absorbed through existing Department activities. In addition, the Department stated that there should be minimal or no cost to any other state agency. The Department noted that the Minnesota Department of Human Services already covers the cost of newborn screening for infants who are covered on Medicaid, Minnesota Care or other subsidized Minnesota Health programs. Finally, the Department indicated that the proposed rules will not affect state revenues. The Department anticipates that the fee will continue to cover the cost of testing.[34]

33. The third requirement imposed by Minn. Stat. § 14.131 asks the Agency to determine whether there are less costly or less intrusive methods to achieve the purposes of the proposed rules. The Department stated in the SONAR that has proposed the least costly and least intrusive methods necessary for achieving the purpose of the rules, which it indicated is to ensure that "all" Minnesota newborns are screened.[35] The Department indicated that the proposed rules will not cause increased monetary costs to the health care system since newborn screening is already conducted in Minnesota. It noted that the only less costly alternative would be not to screen newborns, which would be inconsistent with the existing statutory requirement. In addition, according to the Department, less intrusive methods such as not mandating certain responsibilities each party must carry out will not guarantee that all newborns are screened and referred for evaluation and may result in a newborn being overlooked. Finally, the Department maintains that "the policies and procedures outlined in the proposed rules are established standards that most of the parties should have already adopted."[36] The implication of this statement is that the rules are not intrusive because they are consistent with existing practice.

34. The fourth provision of Minn. Stat. § 14.131 requires the Department to describe any alternative methods that were considered and the reasons they were rejected. In the SONAR, the Department indicated that collecting and testing blood samples is the standard method for screening

[33] SONAR at 4-5.
[34] SONAR at 5.
[35] Of course, this statement is not quite accurate, since parents and guardians retain the right, under Minn. Stat. § 144.125 and the proposed rule, to "opt out" of the screening if they choose. However, it does appear that all Minnesota newborns are screened, with the exception of those whose parent or guardian objects.
[36] SONAR at 5-6.

newborns. The Department relied on its earlier statements that less costly or intrusive methods are not available to accomplish the goals of the screening and on its discussion of performance-based rules for discussion of alternative methods that were considered and the reasons they were rejected.[37]

35. The fifth factor requiring consideration under Minn. Stat. § 14.131 is the probable cost of complying with the proposed rules. The Department indicated in the SONAR that, since newborns are already screened, there should be no increase in cost for parents or birthing centers. The Department stated that the activities required by the rule are generally in place for most responsible parties and primary medical care providers but, to the extent that they are not already in place, they are easily incorporated into existing activities. No comments were received about additional work or cost from the Minnesota Hospital Association, the Minnesota Council of Health Plans, birthing centers or primary care providers, all of whom were represented on the Advisory Committee and the Department anticipated that such parties would incur very limited, if any, new costs as a result of the rules. Finally, the Department reiterated that it is the only government entity that will be affected by any additional costs under the proposed rules and expects any such costs to be minimal.[38]

36. The sixth factor set forth in Minn. Stat. § 14.131 requires an assessment of the probable costs or consequences of not adopting the proposed rule. As stated earlier, the Department asserts that the most significant cost of not adopting the proposed rules is the possibility that a newborn will suffer serious illness or even death as a result of not receiving newborn screening at the earliest possible time. In addition, the Department points out that the proposed rule changes are necessary in order to bring the rule into compliance with statutory changes made in 2003.[39]

37. The seventh factor which Minn. Stat. § 14.131 requires the Department to address is consideration of differences between the proposed rule and existing federal regulations. The Department stated in the SONAR that there are no federal regulations regarding newborn screening and that this is a state function so the proposed rules do not conflict with current federal law and regulations.[40] The Administrative Law Judge agrees that federal law does not govern the screening itself; however, the Department has relied on federal law to support its position that the results of the screening tests cannot be destroyed for two years.[41] This may become significant in light of the language in the 2006 statutory amendments passed by the Legislature requiring the Commissioner to "comply with a destruction request within 45 days after receiving it."[42] This issue is discussed in further detail below in the Rule by Rule Analysis relating to part 4615.0600 of the proposed rules.

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[37] SONAR at 6.
[38] SONAR at 6-7.
[39] SONAR at 7.
[40] SONAR at 7.
[41] 42 C.F.R.493.1105.
[42] Minn. Stat. § 144.128 (5) (2006).

38. The Administrative Law Judge concludes that the Department has fulfilled its obligation under Minn. Stat. § 14.131 to discuss cost and alternative assessments in the SONAR.

B. Performance-Based Regulation

39. Minn. Stat. § 14.131 imposes an additional requirement that the Department explain how it "considered and implemented the legislative policy supporting performance-based regulatory systems set forth in section 14.002" in developing the proposed rules. Section 14.002 states, in relevant part, that "whenever feasible, state agencies must develop rules and regulatory programs that emphasize superior achievement in meeting the agency's regulatory objectives and maximum flexibility for the regulated party and the agency in meeting those goals."

40. The Department explained in the SONAR that it asked the Advisory Committee for input on such standards, asking them (1) whether special situations should be considered in developing the rules; (2) whether there were ways to reduce the burdens of the rules; and (3) whether they had any additional insights on how to improve the rules. The Committee members agreed that the changes to the rules were the best methods to achieve the goal of screening all Minnesota newborns in a timely manner. Members of the Advisory Committee found language originally included in the drafts of parts 4615.0550 (F) and 4615.0600(H) of the proposed rules that would have required parties to use "reasonable efforts" to obtain repeat specimens to be too vague. Instead, the group recommended using the term "best efforts." The Department revised the language of the proposed rules consistent with that advice. In addition, committee members indicated that primary medical care providers sometimes have difficulty getting the newborn screening report from the responsible party and proposed working on efforts to avoid that problem. The Department agreed that it "will work on ways to facilitate communication and will ensure this information is highlighted in the implementation materials."[43] The Advisory Committee also agreed that translated materials provided by the Department would be helpful as would reducing the time-frame for screening and reporting results.

41. The Administrative Law Judge concludes that the Department has satisfied the requirements of Minn. Stat. § 14.131 for assessing the impact of the proposed rules.

C. Consultation with Commissioner of Finance

42. Minn. Stat. § 14.131 also requires that the agency consult with the Commissioner of Finance to help evaluate the fiscal impact and fiscal benefits of the proposed rule on units of local government. The Department noted in its

[43] SONAR at 8.

SONAR that, in September of 2006, prior to publishing the notice of intent to adopt these proposed rules, it sent the Commissioner of Finance copies of the documents it had provided to the Governor's office for review and approval. These documents included the Governor's Office Proposed Rule and SONAR Form, final draft rules, and the nearly-final SONAR. The Department of Finance had no comments.

43. The Administrative Law Judge concludes that the Department has met the requirements set forth in Minn. Stat. § 14.131 for consultation with the Commissioner of Finance regarding the fiscal impact and fiscal benefits of the proposed rules.

D. Cost to Small Businesses and Cities under Minn. Stat. § 14.127

44. Under Minn. Stat. § 14.127, subd. 2, agencies must "determine if the cost of complying with a proposed rule in the first year after the rule takes effect will exceed $25,000 for: (1) any one business that has less than 50 full-time employees; or (2) any one statutory or home rule charter city that has less than ten full-time employees."[44] Although this determination is not required to be included in the SONAR, the statute states that the agency "must make [this] determination . . . before the close of the hearing record" and the Administrative Law Judge must review the determination and approve or disapprove it.

45. In the SONAR, the Department stated that it has considered whether the cost of complying with the proposed rules in the first year after the rule takes effect will exceed $25,000 for any small business or small city and has determined that it will not. The Department's determination is based on its assessment in the SONAR of the probable costs of complying with the proposed rule.[45] The Department asserted that none of the members of the Advisory Committee or the public commented on costs to small business or small cities.[46] No such concerns were raised at the hearing or in comments received from members of the public.

46. The Administrative Law Judge concludes that the Department has met the requirements set forth in Minn. Stat. § 14.127 for determining whether the cost of complying with the proposed rule in the first year after the rule takes effect will exceed $25,000 for any small business or small city.

VIII. Analysis of the Proposed Rules

47. This Report is limited to the discussion of the portions of the proposed rules that received critical comment or otherwise need to be examined. Accordingly, the Report will not discuss each comment or rule part. Several sections of the proposed rules were not opposed by any member of the public and were adequately support by the SONAR. For these reasons, it is

[44] Minn. Stat. § 14.127, subd. 1.
[45] *See* SONAR at 6-7.
[46] SONAR at 10.

unnecessary to engage in a detailed discussion of each part and subpart of the proposed rules in this Report. The Administrative Law Judge specifically finds that the Agency has demonstrated the need for and reasonableness of all rule provisions not specifically discussed in this Report by an affirmative presentation of facts. She also finds that all provisions not specifically discussed are authorized by statute and there are no other problems that would prevent the adoption of the rules.

IX. Broad Issues Relating to the Proposed Rules

A. Retention of Data and Provision of Information to Parents

48. Mark McCann, supervisor of the Department's newborn screening program, testified about the importance of newborn screening in detecting certain harmful or potentially fatal disorders that are not otherwise apparent at birth. He indicated that the newborn screening program screens more than 73,000 newborns each year in Minnesota and "saves the lives or greatly improves the outcome of approximately 100 children who have a confirmed disorder."[47] Mr. McCann asserted that the Department and the newborn screening program "are very committed to informing parents about screening and to following the changes made by the Legislature that obligate hospitals to inform parents of their rights regarding screening."[48]

49. Non-agency testimony in favor of the rule came from two people attending the hearing: Steven Johnson, J.D., Chair of the Newborn Screening Advisory Committee, and Susan Berry, M.D., Professor and Director of the Division of Genetics & Metabolism, Department of Pediatrics, University of Minnesota. Mr. Johnson noted that the prompt discovery through newborn screening that his infant daughter had PKU enabled her to receive treatment long before the health effects otherwise would have been apparent and enabled her to avoid what otherwise may have been significant developmental disabilities. Both witnesses spoke in support of the need for newborn screening, and of the process that is encompassed in the proposed rules.[49]

50. In addition, eight written statements were offered in support of the newborn screening program in general and the proposed rules in particular. The Minnesota Chapter of the American Academy of Pediatrics emphasized that early diagnosis and proper treatment can make the difference between lifelong impairment and healthy development, and supported the rule changes as serving the dual purposes of easy detection and the provision of information to families. The Minnesota Council of Health Plans also stressed the health benefits of early detection of potentially debilitating and sometimes deadly disorders and indicated that the opt-out arrangement ensured the ongoing availability of screening while giving those who object the right to decline the tests. In its view, any attempt to make the program an "opt-in" procedure "could potentially compromise and

[47] Hearing Transcript at 16.
[48] Transcript at 18.
[49] Transcript at 22-25.

undermine this vitally important program." The March of Dimes supported the clarifying language contained in the proposed rules as well as the current "opt-out" system. It also opposed an "opt-in" system because it believes that such an approach could put babies at risk for treatable conditions not being detected. The Mayo Clinic also expressed strong support for the proposed rules. It stated that the innovative public-private partnership between the Department, the University of Minnesota, and the Mayo Clinic College of Medicine in carrying out the Minnesota newborn screening program has led to widespread benefits in protecting the lives and health of newborns, and indicated that adoption of the rules will make the program stronger, more efficient, and able to respond in a timely manner to future opportunities and challenges. The CARES Foundation, a non-profit organization that provides support to individuals affected by congenital adrenal hyperplasia, urged adoption of the proposed rules and expressed support for allowing the Department the flexibility necessary to easily and effectively add new screens as they become available. Richard C. Lussky, M.D., M.P.H., F.A.A.P., the Co-Medical Director of the Newborn Intensive Care Unit of Hennepin County Medical Center, noted that he strongly supports the newborn screening program since he has seen the lives of babies saved because of the expanded screening program, and believes that the proposed rules will make the program more comprehensive, diminish the risk of missing significant findings, and improve communication with health care providers that are providing care to babies with abnormal screens. Christine Doran, the parent of a child who benefited from newborn screening, expressed support for the program and for the proposed rule changes and indicated that the rule changes will strengthen the program and benefit children, families, and communities. She also believed that newborn screening should not be changed to an "opt-in" format because, out of ignorance, parents with no family history of congenital conditions might not undergo the testing. Finally, Sharmini Rogers, M.B.B.S., M.P.H., the Missouri State Genetics Coordinator, also expressed support for the proposed new rules based on a view that they will strengthen the program and ensure the use of a standardized approach. She noted that many states already have similar guidelines in place.[50]

51. While several individuals who testified or wrote in favor of the proposed rules explicitly supported the "opt out" design of the newborn screening program generally and praised the Department's brochure, none of them specifically addressed the questions raised by the Citizens' Council on Health Care (CCHC) and others at the hearing about the extent to which parents or guardians are provided with adequate information before being asked to make a decision about the Department's retention of genetic information.

52. Several individuals who testified at the hearing expressed concerns about the proposed rule. For example, State Representative Mary Liz Holberg testified about the history of the "opt out" nature of the testing procedures and her belief that the Department was slow to implement the 2003 requirements for informing parents of their rights to opt out of testing or to have the blood samples

[50] Ex. L.

and test results destroyed. While acknowledging that the Department has "come a long way," Representative Holberg expressed continuing concerns about the way in which parents were being informed about the testing and the collection and retention of this genetic information. In particular, Representative Holberg stated that the Department is "still not providing a balanced approach in the informational materials to parents." She raised concerns about the Department's indefinite retention of blood samples and the Department offering materials for research purposes without proper information being given to parents.[51] John Tyler testified in support of the idea of newborn testing but said that he is very concerned about the retention of the genetic information by the Department. He also strongly criticized the Department for "illegally" collecting information through its failure to fully implement the requirements imposed by the 2003 law, and requested that the information collected during that time be destroyed.[52] Martin Kellogg asked for clarification about the portion of the statute that creates the "opt out" system, then questioned the constitutionality of such a system. He also pointed out that asking parents to make a decision about "opting out" or even consenting to the screening at the time of birth is very difficult and stressful for the parents. Mr. Kellogg generally expressed his support for the concerns about the collection and retention of genetic information raised by those who had testified before him.[53] Pat Jacobson, a registered nurse who has worked in labor and delivery and has been a public health nurse, reiterated that parents of newborns are "rather frazzled and fatigued," suggested that care providers start educating parents before delivery, and stressed the need to provide continuing education about newborn screening to hospital nurses.[54] Joanne Smith, a certified medical assistant, asked whether the Department's newborn screening brochure would be translated into Somali, and was told by Mark McCann, the newborn screening supervisor, that it would be. She then asked a number of questions relating to the retention and destruction of the blood samples, and expressed concerns about the Department's retention of those samples.[55] Dr. Brian Boyd, a chiropractor and father of two children, ages two years, and eight months, testified that he was unaware that the PKU testing had other testing that went along with it, or that the blood and test results "went to a genetic blood bank" and asked the Department representatives whether information about the screening is given before the birth and whether it can be given during pre-natal visits. Mr. McCann responded that "we require hospitals to inform parents before any specimen testing and collection takes place."[56]

53. Numerous written comments were received both before and after the hearing from members of the public. Many of the individuals and organizations objecting to the proposed rules stated that their foremost concern was the lack of information shared with parents of newborns about the screening itself, and about the retention of individual medical data by the Department. Of

[51] Transcript at 33-38.
[52] Transcript at 38-40.
[53] Transcript at 70-79.
[54] Transcript at 85-86.
[55] Transcript at 29-32.
[56] Transcript at 44.

the 69 requests for hearing, approximately 65 specifically mentioned these concerns. An additional 60 comments were received from individuals who did not attend the hearing but who were concerned about the Department's collection and retention of newborn's blood and test results. Many of the requests for hearing and the written concerns submitted either shortly before or after the hearing came from individuals who either stated that their concerns were based on information they received from the Citizens Council on Health Care (CCHC), or identified concerns that were identical to those set forth by CCHC.

54. Twila Brase, the president of CCHC, testified orally at the hearing and also submitted written post-hearing comments. Ms. Brase reviewed some of the history behind the 2003 statutory changes that required these rule amendments, and testified that her organization was alarmed that the newborn screening had expanded from one test for PKU during 1965-2001, to five tests in 2001, to 53 tests by 2003. Ms. Brase indicated that CCHC had asked the Legislature in 2003 to require informed consent before administering the newborn screening tests and permit parents to request that only the PKU test be performed, but CCHC was only able to obtain passage of legislation permitting parents either to refuse all testing or to permit the testing to be performed but request that the infant's test results and blood specimen be destroyed within two years.[57]

55. In response to the questions and comments made during this rulemaking proceeding about retention of the dried blood spots and access given to others for research purposes, the Department indicated that it intends to place a new page on its website by late spring or early summer addressing the storage and use of specimens.[58] Mr. McCann stated that dried blood spot specimens have been stored in Minnesota since 1997.[59] Typically, all but approximately 30% of the dried blood spot material is used up by the newborn screening.[60] Part of the newborn screening testing is done at the Mayo Clinic, which does not retain any dried blood spots beyond two years.[61] At the hearing, Mr. McCann indicated that, to gain research access to the "anonymized" dried blood spot specimens for future newborn screening test development, academic researchers must go through their Institutional Review Board's approval process for human subjects research approval. He indicated that the Department had received three requests from independent research organizations during the past three years and had provided those researchers with access.[62] In its post-hearing submission, the Department clarified that it had also received a fourth request for access to data during this time period, but had approved only three. The three that the Department approved did not identify individuals because they

[57] Transcript at 44.
[58] Transcript at 64-65, 82.
[59] Transcript at 30, 36-37.
[60] Transcript at 67.
[61] *Id*.
[62] Transcript at 83-85.

used "de-identified" dried blood spots to research new tests for newborn screening.[63]

56. The Department relies heavily on its Newborn Screening brochure as a primary education tool. The brochure, which was provided as an exhibit during the hearing but is not incorporated in the proposed rules, states that the Department will use the blood sample to test for "more than 50 disorders" and lists many of those disorders. It states that the screening will be done and the card with the baby's blood and the test results will be stored at the Department unless the parent refuses in writing.[64] The Department presented no evidence of other information that is provided to a parent before the screening test is performed to help them decide whether to opt out of either the testing or the retention of the blood and the test results. Based upon the information provided during this rulemaking proceeding, it appears that parents are not informed that the Department will maintain the test results for an indefinite period of time; that the parents may decide later to request that the blood sample and test results be destroyed; or that the blood sample may be provided to outside institutions for research purposes. If a parent wishes to "opt out" of retention of the sample and test results, the form that the Department has prepared for the parent to sign does say "a portion of the blood sample may be used for research purposes out of the . . . Department . . . when . . . all information identifying the individual has been removed from the sample." However, that form, which contains other useful information such as a statement that the storage provides "a permanent record" that the screening was completed, a brief blood sample storage policy and some of the reasons for the storage, is not provided to a parent until she or he has already decided to refuse to permit the child's information to be retained.[65]

57. The duties of the responsible parties are set forth in part 4615.0550 of the proposed rules. Subpart B requires that the responsible party "adopt a policy to ensure the parents are informed verbally and in writing about newborn screening prior to specimen collection" including providing the Department's written materials (or other materials approved by the Department) and informing parents of their "right to refuse the screening and the information designated in Minnesota Statutes, section 144.125, subdivision 3." Neither Minn. Stat. § 144.125, subd. 3, nor the provisions of the proposed rules requires that parents be informed that, unless they refuse, the Department will retain the child's blood indefinitely or that it may be shared with researchers without further permission; or that the parents may change their minds later and request that their child's information be destroyed by the Department.

Tennessen Warning

58. CCHC requested that the Department be required to create a Tennessen Warning for parents and that hospitals be required to provide that

[63] Department's Feb. 14, 2007, submission at 4.
[64] Ex. O.
[65] Ex. D, attachment F.

information to parents.[66] A "Tennessen Warning" is the name given to a warning that is required by Minn. Stat. § 13.04, subd. 2, to be given any time an individual is asked to provide a government entity with private or confidential data. The statute requires that a Tennessen warning contain certain elements, including:

> (a) the purpose and intended use of the requested data within the collecting government entity;
>
> (b) whether the individual may refuse or is legally required to supply the requested data;
>
> (c) any known consequence arising from supplying or refusing to supply private or confidential data; and
>
> (d) the identity of other persons or entities authorized by state or federal law to receive the data.

59. In its post-hearing submission filed on February 14, 2007, the Department replied to CCHC's request for a Tennessen warning to be incorporated into the rule. The Department maintains that the Tennessen warning does not apply to the newborn screening situation because the blood is collected by private or non-profit hospitals, not by government entities. The Department further contends that, even if the Tennessen warning does apply, the requirements of the Tennessen warning are essentially contained in its current newborn screening brochure given to parents.[67]

60. After careful consideration, the Administrative Law Judge finds that the Department's contention that the Tennessen warning statute does not apply to the newborn screening program to be flawed. The proposed rules demonstrate that hospitals are merely acting, for a very brief period of time, as agents of the Department in carrying out the newborn screening program. Under the proposed rules, responsible parties must "send the completed specimen card . . . to the department so that it arrives there by 4:30 p.m. on the next business day following collection." It is the Department that collects and retains both the blood samples and the test results; the Department merely relies upon the responsible parties to implement the necessary communications and the actual drawing of blood.

61. Minn. Stat. § 13.05, subd. 11(a) states:

> If a government entity enters into a contract with a private person to perform any of its functions, the government entity shall include in the contract terms that make it clear that all of the data created, collected, received, stored, used, maintained or disseminated by the private person in performing those functions is subject to the

[66] Transcript at 61-62.
[67] Letter from Minnesota Department of Health dated January 12, 2007, page 9.

> requirements of this chapter and that the private person must comply with those requirements as if it were a government entity.

While the Department does not enter into formal contracts with each of the responsible parties in connection with the newborn screening program, the requirements of Minn. Stat. § 144.125 and the proposed rules create a situation that is essentially the same as though the Department were contracting with them. The infants whose blood is being collected and forwarded to the Department and the parents of those children have the same interests at stake as they would were Department personnel coming to the birthing centers and taking the blood directly.

62. The Administrative Law Judge concludes that the requirements of the Tennessen warning do apply to this situation and that a parent or guardian must receive all of the information required by Minn. Stat. § 13.04, subd. 2, before the screening test is done and before the parent or guardian decide whether to "opt out" of the information retention scheme. Furthermore, the Administrative Law Judge concludes that the newborn screening brochure currently used by the Department does not satisfy the requirements of Minn. Stat. § 13.04, subd. 2 (c) or (d). The proposed rule's failure to incorporate the requirements of Minn. Stat. § 13.04, subd. 2, constitutes a defect in parts 4615.0550 (B) and part 4615.0600 of the proposed rules to the extent that these provisions neither require a responsible party to provide a Tennessen warning to the parent or guardian nor require the Department to create a Tennessen warning for responsible parties to use. This defect can be cured by adding language to these two portions of the proposed rules. First, language similar to the following should be added to part 4615.0550, subpart B, item 1 in order to clarify that the warning must be provided to parents by the responsible parties:

> The responsible party shall do all of the following:
>
> * * *
>
> B. adopt a policy to ensure the parents are informed verbally and in writing about newborn screening prior to specimen collection. This includes:
>
> (1) providing the parents of a newborn infant written materials made available by the department's newborn screening program or approved by the program, <u>including materials which fulfill the requirements of Minn. Stat. § 13.04, subd. 2</u>; . . . .

Second, additional language should also be added to part 4615.0600 of the proposed rules requiring that the Department provide language for responsible parties to use to fulfill this requirement. It appears that this could be accomplished by inserting a new item F before the requirement that the Department provide forms requesting destruction of the blood sample and test results. The new item F would require the Department to "provide and make

available to responsible parties or others who request it a written statement that meets the requirements of Minn. Stat. § 13.04, subd. 2." The remaining paragraphs should be re-lettered accordingly. These modifications respond to public comments regarding the proposed rules, are necessary to conform the proposed rules to applicable State law, and would not constitute a substantial change in the proposed rules.

Genetic Information Safeguards

63. During 2006, the Legislature enacted an amendment to the Minnesota Government Data Practices Act (MGDPA). The new provision of the MGDPA, which is codified at Minn. Stat. § 13.386, relates to the treatment of genetic information held by government entities and other persons. This statute defines "genetic information" to include "medical or biological information collected from an individual about a particular genetic condition that is or might be used to provide medical care to that individual or the individual's family members."[68] Subdivision 3 of the statute states:

> *Unless otherwise expressly provided by law,* genetic information about an individual:
>
> (1) may be collected by a government entity, as defined in section 13.02, subdivision 7a, or any other person only with the written informed consent of the individual;
>
> (2) may be used only for purposes to which the individual has given written informed consent;
>
> (3) may be stored only for a period of time to which the individual has given written informed consent; and
>
> (4) may be disseminated only:
>
> (i) with the individual's written informed consent; or
> (ii) if necessary in order to accomplish purposes described by clause (2). A consent to disseminate genetic information under item (i) must be signed and dated. Unless otherwise provided by law, such a consent is valid for one year or for a lesser period specified in the consent.[69]

This provision was effective on August 1, 2006, and applies to genetic information collected on or after that date.

64. Neither the Department nor any witnesses at the hearing or people who submitted written comments addressed the question of whether or how this

[68] Minn. Stat. § 13.386, subd. 1(b).
[69] Minn. Stat. § 13.386, subd. 3 (emphasis added).

provision, which was effective on August 1, 2006 and applies to genetic information collected on or after that date, applies to the newborn screening information. When asked, post-hearing, to comment on the applicability of this statute to the proposed rules, the Department replied that section 13.386, subd. 3, does not apply to the genetic information collected in the newborn screening process because the "opt out" provision for data collection under Minn. Stat. §144.125, subd. 3, exempts it under the "unless otherwise expressly provided by law" language of the MGDPA amendment. In a memorandum dated June 7, 2006, responding to questions raised by the Department of Administration about the MCDPA amendment, Deborah K. McKnight, Legislative Analyst, House of Representatives Research Department, indicated that she would read the phrase "unless otherwise expressly provided by law" to mean that existing Health Department and BCA laws would be kept in place because that clause "allows for laws that require collection or release of genetic information without the subject's consent."

65. Because the legislative scheme established by newborn screening statute provides that the "default" outcome (where parents do not "opt out") is that blood is collected from the infant and sent to the Department,[70] the Administrative Law Judge agrees with the Department's view that the newborn screening statute expressly authorizes the collection of genetic information by the Department and responsible parties without written informed consent, and that the MGDPA amendment therefore does not apply to the initial collection of genetic information from newborns. However, the Administrative Law Judge finds the Department's contention that the "opt-out" nature of the initial testing also expressly authorizes indefinite retention and dissemination of the genetic information for other purposes to lack support in the newborn screening statute. The only direct reference in the newborn screening statute to the ability of the Department to retain the information is contained in Minn. Stat. § 144.125, subd. 3(1), which simply indicates that parents shall be advised that the samples as well as the results of such testing "may be retained by the Department." This can hardly be said to constitute express authority for the Department to retain the information indefinitely. Moreover, while Minn. Stat. § 144.128 specifies that the Commissioner's duties shall include "maintain[ing] a registry of the cases of heritable and congenital disorders detected by the screening program for the purpose of follow-up services," this provision does not provide any support for the Department's current practice of making information obtained from newborn screening available to third parties for research purposes. There is no express authorization in the newborn screening statute for the Department's current practice of retaining the information indefinitely without consent and permitting the information to be used without consent for purposes other than the detection, treatment, and follow-up of heritable and congenital disorders as contemplated by the newborn screening statute.

66. The MGDPA amendment contained in Minn. Stat. § 13.386 reflects a serious concern on the part of the Legislature about the collection and retention

[70] Minn. Stat. § 144.125, subd. 3.

of genetic information and there is no basis for reading an implication into the statute that the Department is exempted from all of its provisions simply because a parent or guardian is given the option of opting out of the information retention system. In fact, if a parent or guardian elects not to opt out of the screening, the Department will retain the baby's genetic information for some period of time, ranging from 45 days to at least two years.[71]

67. Therefore, after careful consideration, the Administrative Law Judge concludes that the newborn screening statute does not expressly authorize the Department to store genetic information indefinitely or disseminate that information to researchers without written informed consent provided by parents.[72] As a result, Minn. Stat. § 13.386 does apply to the proposed rules and the failure to incorporate its requirements into parts 4615.0550 and 4615.0600 constitutes a defect in the rules. This defect may be cured by inserting a new item D following part 4615.0550, item C, of the proposed rules with language similar to the following:

> D. require a parent who chooses not to elect to have the Department destroy the newborn infant's blood sample and test results to sign a form provided by the Department which states the purposes for which the blood and test results will be used, including provision of the child's blood or test results to outside entities for research purposes, and the period of time for which the blood and test results will be stored.

The remaining items in this part would be re-lettered accordingly. Similarly, a new item E should be added to Part 4615.0600 after existing item D which would require the Department to "develop and provide a form for a parent to sign who chooses not to elect to have the Department destroy the newborn infant's blood sample and test results which states the purposes for which the blood and test results will be used, including provision of the child's blood or test results to outside entities for research purposes, and the period of time for which the blood and test results will be stored." Finally, current item F of the proposed rules, which requires the Department to provide forms a parent can use to indicate that they want their infant's blood sample and test results destroyed, should be revised to also require that such forms include statements explaining "the purposes for which the blood and test results will be used, including provision of the child's blood or test results to outside entities for research purposes, and the period of time for which the blood and test results will be stored."[73] These

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[71] *See* discussion of destruction provisions in the Rule by Rule Analysis below.

[72] The Department indicated that it does remove identifying information before providing dried blood spot samples to researchers. Transcript at 84-85; Department's Feb. 14, 2007, Post-Hearing Submission at 4. This rulemaking proceeding did not offer a proper forum for discussion or decision regarding whether DNA may ever be made anonymous, and it appears that there is a debate on this issue. At a minimum, it appears that the Department should notify parents at the time of the initial collection of newborn samples that it will provide blood samples to outside researchers and describe what steps it takes to remove identifying information.

[73] As noted below, other changes have also been recommended to be made to current item F.

modifications will correct the defects in the rules and will not result in rules that are substantially different from the rules as originally proposed.

X. Rule by Rule Analysis

Minnesota Rules Part 4615.0400 – Definitions

Subpart 3 – Newborn Infant

68. As originally proposed, subpart 3 of the proposed rules defined a "newborn infant" as "a child from birth through one month of life." In the SONAR, the Department stated that it chose one month because established medical protocols call for newborns born with certain medical problems and who are being cared for in a neonatal intensive care unit to be screened 24-48 hours after birth, 14 days after birth and 30 days after birth.[74] In comments submitted prior to the hearing, Allina Hospitals and Clinics pointed out that Minn. Stat. § 144.125, subd. 1(1), places the duty to perform testing on institutions "caring for infants 28 days or less of age."

69. Prior to the hearing, the Department proposed to revise subpart 3 to replace the reference to "one month" with 28 days.[75] The modification is necessary for the rule to be consistent with the statute. No one objected to the change and nothing in the rule prevents a hospital or other care provider from performing the screening at 30 days after birth if that is considered medically appropriate. This change is minor in nature and does not render the definition of "newborn infant" substantially different than it was in the original language proposed by the Department.

Subpart 3 - Infant

70. The proposed rules define "infant" to mean a child up to one year of age. CCHC requested that the definition of "infant" be confined to those 28 days old or younger, in keeping with the statute. In response, the Department pointed out that the current law does not define the term "infant." Minn. Stat. § 144.125, subd. 1, merely indicates that the initial testing is to be done by the responsible party before an infant is 28 days old. The Department pointed out that later tests are conducted if the specimen was unsatisfactory or follow-up is needed.

71. Minn. Stat. § 144.128 requires that the Department follow up with the primary care provider after testing and the newborn leaves the hospital, and Minn. Stat. § 144.125 directs the Commissioner to collect screening fees that cover the costs of not only conducting the tests but also the costs of "maintaining a system to follow-up infants with heritable or congenital disorders." The Administrative Law Judge concludes that the Department has shown that it is necessary and reasonable to define infant as up to one year of age in light of the need for retesting of unsatisfactory specimens and the need to conduct follow-up.

[74] SONAR at 12.
[75] Ex. N.

Subpart 4a – Primary Medical Care Provider

72. Primary medical care providers are required to carry out certain duties under the newborn screening rules, including reporting results of diagnostic evaluation of all infants with positive screening results, obtaining and submitting repeat specimens at the request of the Department, providing parents with test results and educational materials, and assisting parents in completing forms in the event that they want their infant's specimen and results destroyed.[76] As originally proposed, the rules defined the term "primary medical care provider" to mean "the physician or clinic identified by the parent as the entity that will be providing the infant's medical care after the infant is discharged from the hospital or from care of the birth attendant" or "the hospital-based physician or nurse practitioner in cases of long-term infant hospitalization." Prior to the hearing, the Department revised the first prong of the definition to refer to "the provider or clinic identified by the parent . . . ." The Department maintains that the reason for this change is that "[t]he term provider covers a broader network of primary medical care providers than just physician. Physicians are not the only ones who care for children. Physician assistants and nurse practitioner[s] also provide primary care to children. This clarifies MDH's and the advisory committee's original intent."[77]

73. The Department's proposed revision of the definition of "primary medical care provider" significantly expands the scope of people affected by the proposed rules. "Provider" is a very broad term that could encompass professionals such as chiropractors and practitioners of alternative medicine such as homeopaths, osteopaths or practitioners of traditional Chinese medicine, among others.

74. Minn. Stat. 14.05, subd. 2, bars an agency from modifying a proposed rule so that it is substantially different from the proposed rule as originally set forth in the notice of intent to adopt rules or notice of hearing. In determining whether a modification is substantially different from the proposed rule, the Administrative Law Judge must consider whether:

(1) the differences are within the scope of the matter announced in the notice of intent to adopt or notice of hearing and are in character with the issues raised in that notice;

(2) the differences are a logical outgrowth of the contents of the notice of intent to adopt or notice of hearing and the comments submitted in response to the notice; and

(3) the notice of intent to adopt or notice of hearing provided fair warning that the outcome of that rulemaking proceeding could be the rule in question.[78]

[76] See Part 4615.0700 of the proposed rules.
[77] Ex. N.
[78] Minn. Stat. § 14.05, subd. 2(b).

In analyzing the "fair warning" requirement quoted above, the Administrative Law Judge must consider the following factors:

> (1) the extent to which persons who will be affected by the rule should have understood that the rulemaking proceeding on which it is based could affect their interests;
>
> (2) the extent to which the subject matter of the rule or issues determined by the rule are different from the subject matter or issues contained in the notice of intent to adopt or notice of hearings; and
>
> (3) the extent to which the effects of the rule differ from the effects of the proposed rule contained in the notice of intent to adopt or notice of hearing.[79]

75. A review of the organizations and individuals who were involved in the Newborn Screening Rule Advisory Committee and who were notified of the request for comments on the proposed rules and of the intent to adopt the proposed rules pursuant to the required notice given in rulemaking proceedings and the Department's Additional Notice Plan does not indicate that a broad spectrum of providers outside of traditional medical providers were involved or notified of this rulemaking proceeding.[80] On the contrary, the parties who have been notified of the rulemaking proceedings have included organizations such as the Minnesota Medical Association, the Minnesota Academy of Family Physicians, the Minnesota Council of Health Plans and the Minnesota Nurses Association. Nor would the language of parts 4615.0400, subp. 4a, or 4615.0755, subp. 6a, as originally proposed, constitute "fair warning" to people who were not "physicians" or "clinics" that the rules might ultimately be expanded to include them among the "primary medical care providers" responsible for carrying out various duties under the rule. Given the scope of these duties, and the varied approaches to health care represented by these kinds of providers, it is reasonable to conclude that the effect of including them within the definition of "primary medical care provider" would be very significant. Therefore, the Administrative Law Judge concludes that the proposed modification in the language of this portion of the rules would render the rule substantially different from the rule as originally proposed, and constitutes a substantial change.

76. The language of this rule part as originally proposed at the time the proposed rules were published in the State Register was shown to be both needed and reasonable to accomplish the intent of the Department (as stated in the Department's proposed modification) to broaden the scope of "primary medical care provider" to include physician assistants and nurse practitioners. Because both physician assistants and nurse practitioners practice under the supervision of a physician, it appears that their provision of primary care to

[79] Minn. Stat. § 14.05. subd. 2(c).
[80] *See* Findings 5, 11, 15, and 28, and SONAR, attachment D.

children would logically fall within the terms "physician or clinic." Should the Department wish to revert to the "physician or clinic" language originally proposed, the substantial change issue would be avoided and this portion of the rule would not be defective.

Subpart 5 – Responsible Party

77. As originally proposed, the Department sought to amend the current definition of "responsible party" to mean the administrative officer or other person in charge of "each institution caring for newborn infants one month or less of age or the person required by Minnesota Statutes, section 144.215, to register the birth of the newborn infant." The SONAR indicates that the proposal was made to clarify and broaden the definition to include all potential birthing centers or birth attendants and to reflect the intent of the current statute. The Department also wished to clarify in the rules that the definition is limited to institutions that care for newborns that are one month old or less, in order to distinguish the "responsible party" from the "primary medical care provider." In response to written comments submitted by Allina Hospitals and Clinics dated December 29, 2006, the Department submitted a change to the proposed language during the January 23, 2007, rulemaking hearing seeking to clarify that "the nurse midwife or midwife in attendance at the birth" is a "responsible party" under the rule. The Department proposed adding the phrase "or the nurse midwife or midwife in attendance at the birth" before the period at the end of the definition in order to "make the rule clearer and more consistent with the statute."[81]

78. Because the newborn screening statute already specifies in Minn. Stat. §144.125, subd. 1, that the duty to perform testing is shared by "the nurse midwife or midwife in attendance at the birth," the modification made to the proposed rules is consistent with the statute and does not impermissibly expand the scope of the definition. The proposed rule, as modified, clarifies but does not go beyond the statutory language, and has been shown to be needed and reasonable to reflect the intent of the statute. The modification does not result in a rule that is substantially different than the rule as originally proposed.

Minnesota Rules Part 4615.0550 – Duties of Responsible Parties Involved in Newborn Screening Program

79. Due to statutory changes and obsolete provisions, the Department proposes to repeal current rule part 4615.0500 relating to the duties of responsible parties and adopt a new part 4615.0550 describing those responsibilities. In its SONAR, the Department asserts that the majority of the amendments reflect current medical practices.

[81] Ex. N. *See* Minn. Stat. § 144.215.

Use of "Parent" and "Parents" in the Proposed Rule

80. Throughout part 4615.0550, it appears that the words "parent" and "parents" are used interchangeably.[82] The plural form of the word is used in items B and B(1), both the singular and the plural forms are used in items B(2) and C, and the singular form is used in items D, G, L, and M. The SONAR does not discuss why these distinctions were made. The newborn screening statute itself also uses both the singular and plural forms of the word "parent." Minn. Stat. § 144.125, subd. 3, requires that "parents" be advised of their options with respect to testing and information retention and states that, if the "parents" object in writing to testing or wish to require destruction of blood samples and test results, a form must be signed by "a parent or legal guardian." The statute thereby suggests that only one parent needs to sign a waiver form or destruction request, but both parents, if present, should be advised of their ability to object to the testing or request destruction of samples and results.

81. For the most part, the proposed rules appear to be consistent with this implicit legislative intent. It is reasonable and in keeping with the statute to use the plural form in items B and B(1) to ensure that "parents" receive information about newborn screening. It is also reasonable and in keeping with the statute to use the singular form in items D, G, L, and M to acknowledge that one parent may sign a destruction or waiver form, complete the newborn screening card, and designate the primary medical care provider.

82. However, the use of both the singular and the plural forms of the word "parent" in items B(2) and C of the proposed rules is more troubling and may cause confusion as responsible parties undertake their responsibilities under the rule. Consistent with the statute, item B(2) places a duty on responsible parties to inform the "parents" that their newborn will be screened; however, contrary to the statute, the rule goes on to say that the information provided shall include the "parent's" right to refuse the screening. The latter singular reference implies that only one parent has the right to refuse the screening and is unduly vague and contrary to the language in Minn. Stat. § 144.125, subd. 3, that the "parents" have the ability to object to the testing or request destruction of samples and tests. This defect may be corrected by replacing the word "parent's" in the last sentence of item B(2) with the word "parents'." Similarly, item C is consistent with the statute when it requires a "parent" who refuses newborn screening to sign a waiver form, but inconsistent with the statute when it indicates that a copy of the form must be sent to the Commissioner within one week from the time the "parents" sign the form. The latter reference to "parents" in the plural implies that both parents must sign the waiver form and is unduly vague and contrary to the language in Minn. Stat. § 144.125, subd. 3(3)(ii), that the form must be signed by "a parent." This defect may be corrected by replacing the word "parents" in the last sentence of item C with the word "parent." It is important that responsible parties and parents understand that, under the newborn screening statute, forms may be signed by

[82] Part 4615.0400, subp. 3b, of the proposed rules defines "parent" as "the presumptive biological parent or legal guardian of the newborn infant at the time of the testing."

just one parent and the signatures of both parents are not required. Such an approach is reasonable since in some situations one parent is not identified or not present.

Item C

83. Item C of the proposed rules requires that copies of the waiver form signed by a parent who refuses newborn screening be forwarded to the Department as well as maintained in the infant's medical record. In the SONAR, the Department explained that the Department wishes to be informed if parents elect not to screen their infant because the Department tracks whether or not infants have newborn screening specimens submitted to ensure no babies are missed. Although Minn. Stat. § 144.125, subd. 3, only refers to the need to make the waiver form part of the infant's medical record, it is reasonable for the Department to receive a copy as well to ensure that no infant has been overlooked. Item C, as proposed, has been shown to be needed and reasonable.

Item D

84. CCHC objected to the requirement in item D requiring that copies of the signed form asking for destruction of an infant's blood sample and results be sent to the Department since that requirement is not included in the statute. CCHC also recommended that the form be revised to delete the requirement that the signature on the form be witnessed because it contends that that requirement imposes a potential barrier to the exercise of parental rights. The Department indicated in response that it proposed this measure to add procedural detail consistent with the 2003 legislative changes requiring this request to be in writing. The Department further explained that it required a witness signature in addition to the parental signature in order to establish the identity of the parent. The Administrative Law Judge concludes that the Department has shown that it is necessary and reasonable for item D of the proposed rules to require that the request for destruction form be forwarded to the Department to ensure that the Department in fact takes appropriate action to destroy that information. Although the statute does not expressly require the form to be sent to the Department, it is logical to require that step to ensure that the Department has notice that the parent has requested that the sample and test results be destroyed. Since the form used by the Department is not incorporated in the rules, it is not properly at issue in this rulemaking proceeding. The Department is free to consider whether it should revise the form in response to CCHC's comments.

Item G

85. Item G of the proposed rules states that the responsible party shall "accurately complete all fields on the newborn screening card including demographic information and primary medical care provider information as provided by the parent." Some members of the Newborn Screening Rule Advisory Committee who represented "responsible parties" under the rule raised

concerns about how the required information could be included on the screening card where the primary medical care provider was unknown.[83] Allina Hospitals and Clinics also raised the same concern where the parent is unavailable, or unable or unwilling to identify a primary medical care provider.[84] The Department suggested in the SONAR that, in situations where no primary medical care provider was known, hospitals could insert the name of a hospital contact person in that space. Allina suggested that this be spelled out in the rule. In its January 11, 2007, response to Allina's comments, the Department again noted that, where it is not possible to name the primary medical care provider, hospitals can include the name of a contact. However, the Department indicated that it is not willing to change the proposed rules to incorporate this approach because it does not want to encourage this practice.[85]

86. The Administrative Law Judge finds that item G has been shown to be needed and reasonable as proposed to ensure that the Department has the most accurate information available and is able to follow-up with newborns who test positive for a disorder as soon as possible. However, the Administrative Law Judge recommends that the Department reconsider adding language to item G instructing responsible parties to insert the name of a contact person when a parent or guardian is unavailable or is unable or unwilling to identify a primary medical care provider. Given the significant concerns the Department expressed throughout the rulemaking process about its ability to have very prompt contact with the parents of an infant whose test results are positive, this would appear to be an important instruction to include in the rule as guidance for responsible parties. If the Department elects not to follow this recommendation, it does not render the proposed rules defective for purposes of chapter 14.

Additional Concerns

87. CCHC made a number of other suggestions for revisions to part 4615.0550, several of which are addressed in the defect findings above relating to the Tennessen warning and MGDPA genetic information amendment. Other revisions suggested by CCHC regarding changes in the dissemination and posting of newborn screening information (such as requiring responsible parties to provide parents with a list of private testing options, requiring hospitals to post notices about the newborn testing decision in each patient room used by women in labor, requiring responsible parties to distribute and discuss MDH information about the risks and benefits of newborn screening prior to hospital admission, and requiring the Department to maintain an updated list of all conditions for which children are tested and ensure that it is available online and provided to parents) are not required by law. As a result, the proposed rules are not rendered defective by their failure to include them. Some of the other revisions CCHC recommended, such as specific changes in the newborn screening brochure and forms used by the Department, are not subjects that can be addressed during this rulemaking proceeding. Of course, the Department may

[83] SONAR at 8.
[84] Ex. I.
[85] Ex. I.

wish to consider whether some of these modifications should be made as a matter of public policy.

88. Part 4615.0550 of the proposed rules, with the modifications suggested above to correct the defects in items B(2) and C, has been shown to be needed and reasonable to delineate the responsibilities of responsible parties and ensure that newborns are screened in a timely manner and receive follow-up if the test results are positive. The modifications serve to correct defects in the rules, render them consistent with the governing statute, and clarify the rule provisions, and do not result in a rule that is substantially different from the rule as originally proposed.

Minnesota Rules Part 4615.0600 – Duties of Department of Health

89. As noted above, Minn. Stat. § 144.128 was amended during the 2006 legislative session to require, in connection with the newborn screening program, that the Commissioner of Health "(4) prepare a separate form for use by parents or by adults who were tested as minors to direct that blood samples and test results be destroyed; (5) comply with a destruction request within 45 days after receiving it; [and] (6) notify individuals who request destruction of samples and test results that the samples and test results have been destroyed . . . ."[86] In contrast to the 45-day destruction timeline contained in these 2006 amendments, the 2003 amendments to Minn. Stat. § 144.125, subd. 3, state that parents may "elect to have the tests but . . . require that all blood samples and records of test results be destroyed within 24 months of the testing."

90. Item F of part 4615.0600 of the proposed rules requires the Department to "provide forms a parent can use to indicate that they want their infant's blood sample and test results destroyed after two years from the time of screening." The SONAR indicated that this provision was added as a result of the 2003 statutory changes to Minn. Stat. § 144.125, subd. 3.[87] CCHC requested that the Department add requirements to this rule part that follow the 2006 law requiring a separate form for use by parents and adults who request destruction of their results and blood specimens. CCHC also asked the Department to reflect in the proposed rules that it will comply with the destruction request in 45 days, and it will notify those submitting destruction requests that their data and blood specimen have been destroyed.

91. The Department attached a copy of the form the Department referenced in Item F to the SONAR.[88] That form is clearly designed solely for parents or guardians, not for adults who are requesting destruction of their own records. No evidence or testimony was provided to show that the Department has designed or intends to design a form for use by adults who wish to direct that their own samples and test results be destroyed, as required by Minn. Stat. § 144.128 (4). Nor was there any evidence or testimony about how the

[86] 2006 Minn. Laws, Chapter 253, Section 9.
[87] SONAR at 20.
[88] SONAR, Attachment F.

Department notifies, or intends to notify, either parents or adults who were tested as minors that it has complied with their requests to have blood samples and test results destroyed, as required by Minn. Stat. § 144.128 (6). Finally, nothing in the rule addresses the requirement that the Department comply with a destruction request within 45 days after receiving it, as required by Minn. Stat. § 144.128 (5). In fact, subpart F of the proposed rules specifies a two-year timeline for destruction of the blood sample and test results. The two-year timeline is apparently based on the language in Minn. Stat. §144.125, subd. 3(3)(ii), permitting parents the option "to elect to have the tests but to require that all blood samples and records of test results be destroyed within 24 months of the testing."

92. After the hearing, the Administrative Law Judge asked the Department to explain why the proposed rules did not reflect the 2006 changes to Minn. Stat. § 144.128. The Department responded that there was no need to insert that statutory language into the rule because the statutory language was clear and the Department could simply follow the requirements of the statute. The Department further indicated that it had resolved the apparent conflict between the "within 24 months" language in section 144.125, subd. 3(3)(ii), and the "within 45 days" language in section 144.128 (5) by interpreting the "24 months" language to apply only to destruction requests made by parents of infants who are tested at birth or shortly thereafter and interpreting the "45 days" language in section 144.128 to apply only to destruction requests made by adults who were tested as minors or destruction requests by parents of older children. The Department indicated that, if the law was meant to be 45 days for all destruction requests, Minn. Stat. § 144.125 would have been amended in 2006 as well.

93. The Administrative Law Judge is not persuaded by the Department's assertion that the statutory language of 144.128 is so clear that no rule is needed to implement it. The fact that the Department did, in fact, choose to set forth in rules its similar statutory obligations to develop and make available forms for parents to decline newborn screening (see item E) and provide forms a parent can use to indicate that they want their infant's blood sample and test results destroyed (see item F) undermines the Department's contention. Moreover, the Department is required by virtue of the 2006 amendments not only to develop and make available forms for parents to decline the newborn screening and to provide forms a parent can use to request that her child's blood samples and results be destroyed, but also to develop and make available forms to be used by adults who were tested as minors. Similarly, the Department is required to have a system to notify people when it has complied with their destruction requests. Each numbered phrase in Minn. Stat. § 144.128 states a separate, independent duty of the Commissioner of Health.

94. The question of how to interpret and implement the conflicting timelines was discussed at the hearing. Ms. Joanne Smith asked how long the Department has been storing blood samples from newborn screening. Mark McCann, the Department's witness, stated that "[d]ried blood spot specimens

have been stored in Minnesota since 1997."[89] Ms. Smith also asked why the rule says the Department will destroy specimens "within 24 months" rather than immediately. Mr. McCann indicated in response that "dried blood spot specimens can be destroyed before 24 months. The reason we had 24 months written in the 2003 statutory changes was actually not only is the dried blood spot specimen requested to be destroyed, but the electronic record of any test results to be destroyed. We are committed by federal law to retain electronic record results for a minimum of two years. Any parent that has requested a dried blood spot specimen to be destroyed prior to that two-year window we certainly will honor and have honored."[90] Mr. McCann further testified that the Department typically destroys the blood spot specimens themselves within a couple of weeks from receipt of the formal destruction request.[91] This discussion provides a reasonable approach to interpret and implement the timelines. The rule language could be modified to state that the Department will destroy blood samples within 45 days of receipt of the destruction request and the Department will destroy test results within 45 days of receipt of the destruction request or as soon as permitted under federal law, whichever is later. Such an approach would be consistent with both the state and the federal laws.[92]

95. The Administrative Law Judge concludes that the Department's inclusion of the phrase "after two years" in item F, along with its failure to incorporate any of the 2006 statutory changes into part 4615.0600 (including the requirements that the Department provide a form for use by parents or by adults who were tested as minors to request destruction of their genetic information, blood samples and test results be destroyed within 45 days, and the Department notify individuals once their information has been destroyed) is unreasonable and contrary to the newborn screening statute, and constitutes a defect in the rule. The Administrative Law Judge recommends that the Department cure this defect consistent with the discussion above by revising item F and inserting new items G-I after it using language similar to the following:

F. provide forms parents can use to indicate that they want their infant's blood sample and test results destroyed ~~after two years from the time of screening~~;

G. <u>provide forms adults who were tested as minors can use to indicate that they want their blood sample and test results destroyed;</u>

H. <u>destroy blood samples within 45 days of receipt of a destruction request and destroy test results within 45 days of</u>

[89] Transcript at 30.
[90] Transcript at 30-31. After the hearing, the Department clarified that the federal requirement at issue is set forth in the Clinical Laboratory Improvement Act. See 42 C.F.R. § 493.1105(a).
[91] Transcript at 30-31.
[92] Because section 144.125, subd. 3, states that the blood samples and test results should be destroyed "within 24 months," any rule that requires earlier destruction is still consistent with the statute.

receipt of the destruction request or as soon as permitted under federal law, whichever is later;

I. notify individuals who request destruction of samples and test results within ten business days of when the samples and test results have been destroyed . . . .

The remaining items in this part of the proposed rules should be re-lettered as appropriate. These modifications are needed to conform the rule to applicable statute and would not render the rule substantially different from the rule as originally proposed.

Minnesota Rules Part 4615.0700 – Duties of Primary Medical Care Provider

96. Part 4615.0700 of the proposed rules sets forth numerous duties that are expected to be performed by the primary medical care provider in connection with the newborn screening rules. In written comments filed on the proposed rules on December 29, 2006, Allina Hospitals and Clinics expressed concerns that the rules impose a number of duties on "physicians or clinics whom parents identify" as the providers responsible for the infant's care which are not authorized by statute.[93] In response, the Department asserted that the proposed rules are consistent with the legislative intent reflected in the newborn screening statute that efforts would be made to follow up after initial screening. The Department further contended that physicians in Minnesota have already been doing this work. The Department also emphasized that the burden associated with the proposed rules imposed on any one provider is likely to be relatively light, since only approximately 100 out of 73,000 babies born each year in Minnesota are found to have one of the disorders that are the subject of the screening.[94]

97. Minn. Stat. § 144.128 imposes duties on the Commissioner that go beyond testing by, for example, requiring the Commissioner to notify the physicians of newborns of test results, make referrals for necessary treatment, and "maintain a registry of the cases of disorders detected by the screening program for the purpose of follow-up services." Moreover, Minn. Stat. § 144.125, subd. 1, directs the Commissioner to collect fees that cover both the costs of testing and the costs of "implementing and maintaining a system to follow-up infants with heritable or congenital disorders." Therefore, it is evident that the Legislature intended the Department to conduct follow-up after initial screening. The primary medical care providers are the logical persons with whom the Department would need to be in contact to conduct appropriate follow-up, since they continue to be involved in providing care to infants who test positive for one of the disorders. All of the responsibilities imposed on primary medical care providers under the proposed rules, such as arranging for follow-up testing, providing test results and educational materials to parents of an infant who had a positive screening result, and reporting back to the Department the results of a

[93] Ex. I.
[94] Ex. I.

diagnostic evaluation of such infants (or requesting that an appropriate specialist do so), are reasonably related to the statutory scheme requiring follow-up for all infants whose initial tests are positive. Because it is necessary to impose these duties on the primary medical provider in order to ensure effective follow-up, the Administrative Law Judge concludes that the duties of the primary medical care provider set forth in the rule are authorized by Minn. Stat. §§ 144.125 and 144.128. The Administrative Law Judge concludes that the proposed rules do not inappropriately impose duties on primary medical care providers that exceed the scope of the statute.

98. As originally proposed, subpart 3 stated, "If the primary medical care provider provides care to an infant whose birth was not attended by one of the parties listed in this part or part 4615.0550 to 4615.0600, the primary medical care provider shall give parents of an infant written materials on newborn screening made available by the department's newborn screening program or approved by the program." In the SONAR, the Department indicated that this subpart was intended to "ensure that parents who gave birth to a child in a nontraditional setting are made aware of newborn screening so that they can have their child screened."[95] Allina Hospitals and Clinics commented that this subpart did not make sense as written, and the Department agreed. At the rule hearing, the Department modified the language at the beginning of the subpart to instead refer to situations in which the primary medical care provider provides care to an infant whose "birth was only attended by the parent(s) of the child . . . ." The Department indicated that its intent was to require that, if one or both parents were the only persons present at the birth, the primary medical care provider must give the parents the written material on newborn screening that is made available by the Department.[96]

99. The proposed rule, as modified, has been shown to be necessary and reasonable to clarify when the primary medical care provider is responsible for providing information on newborn screening. The modification does not result in a rule that is substantially different than the rule as originally proposed. While the modification does address Allina's concern, the Department may wish to consider whether the rule as modified reaches all of the situations that were intended to be encompassed. For example, the rule as modified seems to suggest that primary care physicians need not provide newborn screening information where people other than the parent(s), but not people in a position to notify the parent(s) of the newborn screening program, were present at the birth. For example, if a baby were born in a taxicab and the birth were "attended" by the cab driver, the cab driver likely would not provide the parent(s) with newborn screening materials. Yet the parent(s) would not fall under the modified language of 4615.0700, subp. 3, because the birth was not attended only by the parent(s). The Department may wish to review this rule further and adjust the language to clarify whether it merely intends to cover situations where the birth is attended only by the parent(s) or whether it also intends to encompass those circumstances where others who are not normally involved in attending a birth

[95] SONAR at 22.
[96] Ex. I.

might also be present. Perhaps a somewhat different approach would be preferable, such as requiring the primary medical care provider to offer newborn screening materials with respect to any infant whose birth did not occur at a birthing center or was not attended by a nurse midwife, midwife or other medical provider. If the Department chooses to modify the language of the proposed rule in one of these ways, it would not constitute a substantial change in the rule.

Minnesota Rules Part 4615.0760 – Responsibilities of Department of Health

Subpart 4 – Registry of Cases

100. In its post-hearing comments, CCHC pointed out that subpart 4 requires the Department to update its registry of patients diagnosed with a disease through the newborn screening program "by direct contact with the patient or parent of a patient who is less than 21 years of age to determine their address and their need for medical treatment services, educational materials, and counseling related to their disease." CCHC suggested that the age specified in the proposed rules should be 17 rather than 21 because people who are 18 or older have the right to decide for themselves whether and what private information to share with the Department. The Department acknowledged that 18 is the age of majority, but replied that many of the affected children remain eligible for services such as special education until they are 21 and that these young adults "are just making the transition to adulthood." Furthermore, the Department stated, "We need to ensure that members of this fragile group are receiving appropriate services. Often, the parent is the one who knows where the child is living. In addition, there are children who are over 18 years old but remain on their parent's health insurance while at college." Therefore, the Department declined to make the suggested changes.

101. The reasons proffered by the Department in support of its selection of age 21 are not sufficient to overcome the fact that, as a matter of law, an 18-year-old has the right to determine what, if any, private health information should be released to the Department. The conflict between the proposed rules and state law establishing 18 as the age of majority constitutes a defect in the rule. To cure this defect, the Administrative Law Judge recommends that the Department change this provision to read that the Department will update the registry "by direct contact with a patient if the patient is at least 18 years of age, or by direct contact with the parent of a patient if the patient is less than 18 years of age." Use of this or similar language will make it clear that the Department must obtain health information from patients themselves if they are no longer minors. If the parents' home is the last known address the Department has for an 18-year-old, the inquiry could be still be sent to the parents' home but should be addressed to the young adult. If the rule provision is revised as suggested, it would serve to clarify the rule and bring it into conformity with state law, and would not constitute a substantial change from the language of rules as originally proposed.

Based on the foregoing Findings of Fact, the Administrative Law Judge makes the following:

CONCLUSIONS

1. The Minnesota Department of Health gave proper notice in this matter.

2. The Department has fulfilled the procedural requirements of Minn. Stat. § 14.14 and all other procedural requirements of law or rule.

3. The Department has demonstrated its statutory authority to adopt the proposed rules, and has fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat. §§ 14.05, subd. 1, 14.15, subd. 3, and 14.50 (i) and (ii), except as noted in Findings 62, 67, 82, 95, and 101.

4. The Department has demonstrated the need for and reasonableness of the other portions of the proposed rules by an affirmative presentation of facts in the record within the meaning of Minn. Stat. §§ 14.14, subd. 4 and 14.50 (iii), except as noted in Finding 95.

5. The additions and amendments to the proposed rules suggested by the Department after publication of the proposed rules in the State Register are not substantially different from the proposed rules as published in the State Register within the meaning of Minn. Stat. § 14.05, subd. 2, and 14.15, subd. 3, except as noted in Finding 75.

6. The Administrative Law Judge has suggested action to correct the defects cited in Conclusions 3, 4, and 5, as noted in Findings 62, 67, 76, 82, 95, and 101**.**

7. Due to Conclusions 3, 4, and 5, this Report has been submitted to the Chief Administrative Law Judge for his approval pursuant to Minn. Stat. § 14.15, subd. 3.

8. Any Findings that might properly be termed Conclusions and any Conclusions that might properly be termed Findings are hereby adopted as such.

9. A Finding or Conclusion of need and reasonableness in regard to any particular rule subsection does not preclude and should not discourage the Department from further modification of the proposed rules based upon an examination of the public comments, provided that the rule finally adopted is based upon facts as appearing in this rule hearing record.

Based upon the foregoing Conclusions, the Administrative Law Judge makes the following:

RECOMMENDATION

IT IS HEREBY RECOMMENDED that the proposed amended rules be adopted, except where noted otherwise.

Dated: March 23, 2007

s/Barbara L. Neilson
BARBARA L. NEILSON
Administrative Law Judge

Transcript Prepared by Paradigm Reporting & Captioning, Inc.
(One volume)